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Single Day Event

Hybrid Trial-Fantasy of a data manager

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Agenda

- What is a Hybrid Trial?
- What are the pros and cons of hybrid trials?
- What kind of Hybrid trial I was involved in?
- What kind of hybrid trials do we have in the market.
- Fantasy

What is Hybrid Trial?

What are hybrid trials?

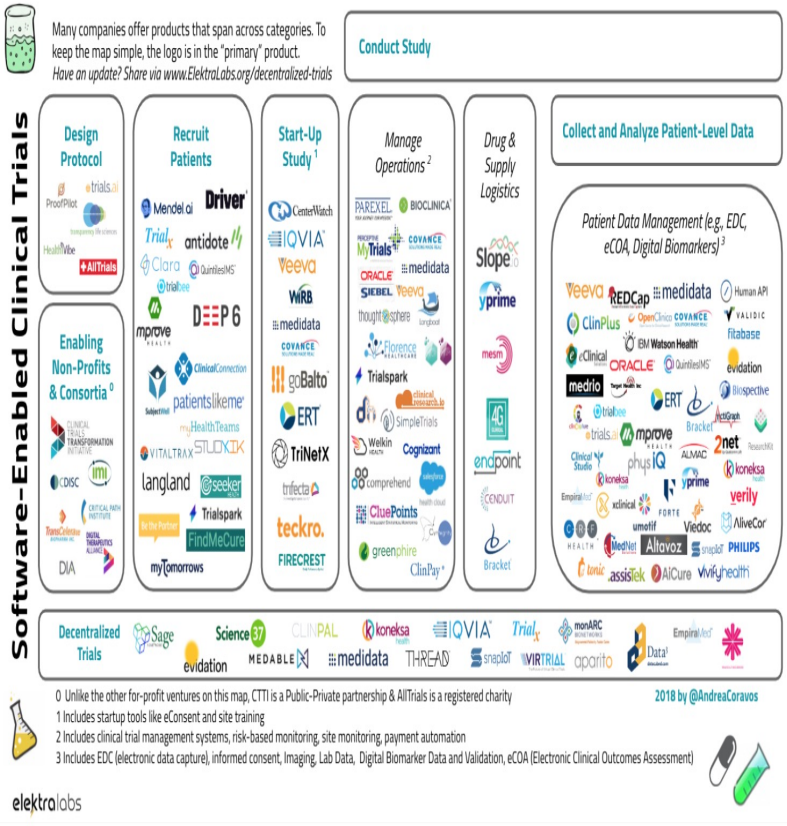
As per definition of FDA:

> "*Any trial where there is decentralization of clinical operations using technology like mobile devices, handheld devices to name a few*"

Few call it as site less trials, few call it Decentralized trials (DCT's), direct to patient trials (DPT's), Virtual trials and site less trials.

Results from recent summit conducted by oracle life sciences found that "none of the participants had worked on a decentralized trial which was 100% decentralized"

Impact of Covid-19 on Hybrid Trial Adoption: One which was considered a Futuristic technology just couple of years back is now considered the need of the hour.



What are the pros and cons of hybrid trials?

Benefits:

- Site visit and maintenance costs are reduced.
- The drop out rate in clinical trials is estimated to be around 50-80% because of travel time, location of sites. This can be reduced by having high retention rates.
- Helps in participation of people with disabilities

Challenges (What's preventing us from achieving 100% decentralization):

- Person participating in trial may not have knowledge of how to use the device, it’s a frequent issue with aged populations
- Place where trial is conducted may not be as sterile as a site leading to lack of accuracy in data
- Some of the data collected using MRI or Biopsy collection in some of the trials is not feasible.
- Handling of device by the participants may affect the quality of data that is being generated
- Increased costs for use of these technologies(Depends on what technology is being used to collect data).

What kind of Hybrid trial I was involved in?

My experience in Hybrid trials:

I have worked in 2 trials that involved virtual components:

- Where there was use of devices or tools to collect data that was directly obtained similar to raw extracts.
- Where there is collection of Patient reported outcomes(ePRO)/Dairy data.

What kind of Hybrid trial I was involved in?

What happened in the first trial:

- There was direct reading of data by the device and integration into CDMS system.
- There was no human intervention of recording data unlike traditional trials.
- What kind of data was integrated:
  - Around 40% of the data was integrated, best examples that I can provide is Vital signs, labs and ECG data.

What worked well:

- There was no cleaning required by data managers or there was least intervention by data managers.
- There were only 3-10 queries raised on whole of this data through out the study.
- How it helped fastening of clinical trial conduct: Data was such that it could have been picked up directly to populate in your Study data tabulation module datasets(SDTM datasets)

What kind of Hybrid trial I was involved in?

- The flow of data became more streamlined from data collection into population in SDTM datasets.
- This will help by increased data quality, Accuracy and faster reporting.

What were the problems faced:

- There was no cleaning required by data managers or there was least intervention by data managers.
- As most of the data is integrated directly from the device even if there were any queries then they had to be raised on Demographics or forms which were open to entry by sites.
- Responses were normally a confirmation of data and there were no changes to data as such.
- Implementation of such technology in the first instance may be a challenge as most of the people at sites or even the CRO's won't have experience in handling such device or flow of data

What kind of Hybrid trial I was involved in?

- There was usage of devices to automate collection of data but the way the technology is used, handled can make a lot of difference in data processing and data quality.
- Data collected can also be made to be assembled in SDTM format at vendors who provide such services so that there can be faster integration into SDTM datasets.

Here are list of datasets that can be collected using sensors/ones which can be automated

Full decentralisation	Partial decentralisation	Can be decentralised in future
VS	DM	CO
EG	EX	CM
QS/ePRO	MH	SU
	DV	AE
	IE	
	PE	
	PC	
	LB	

What kind of Hybrid trial I was involved in?

Some practical difficulties faced during reconciliation of data.

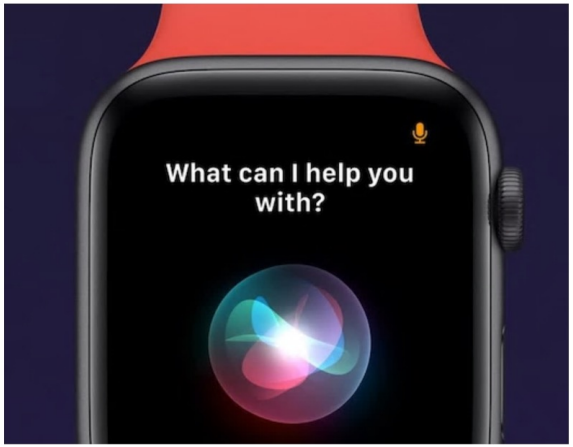
- There can be increased complexities in reconciliation when devices are switched off due to low battery there by preventing the automatic data capture.
- Always Keep suggest to refresh the data so that vendor has the most recent data when they send the transfer to CRO/Pharma companies.
- There can be instances where the protocol deviations increase because patients doesn't record the data on time or within protocol specified time frame there by increasing number of protocol deviation as well increasing chances of excluding data because of such analysis.
- Query management when discrepancies occur can prove to be cumbersome to handle. Have a clear plan/map of handling discrepancies in such cases.
- Most of the vendors promise that there need not be any intervention by Data management or sometimes promise that such incidence doesn't occur on ePRO/Dairy data but there can be some challenges like mentioned above.

What kind of hybrid trials do we have in the market now?

We have different vendors who are providing different kinds of packages:

- We have few who provide only few solutions like use of some of their virtual devices
- We have few more who have started providing solutions from eConsent to eSignature.

How does these work?



What is my fantasy?

Fantasy is to **create an ecosystem for clinical trails** where efficiencies can be built using deployment of virtual components and automation technologies.

Patient enrollment- There is butcher house in UK, it connects to the mobile device of a person who passes by the store. Once the device is connected it pushes offers in its store using blue tooth or wifi technology about what offers they have in the store. Can we have similar one at sites or hospitals.

Imagine enrolling people using technology for all people who complained of fever and who visited clinics or hospitals. There is more likely hood of increased participation if we can target the right population.

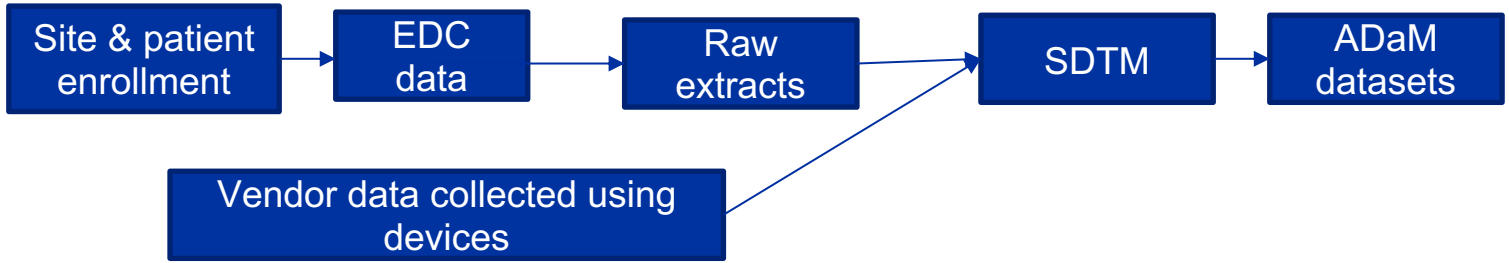
Use the vendors who are providing eConsent to eSignature package for conduct of clinical trial by making it more appealing to subjects who participate in trials.

What is my fantasy?

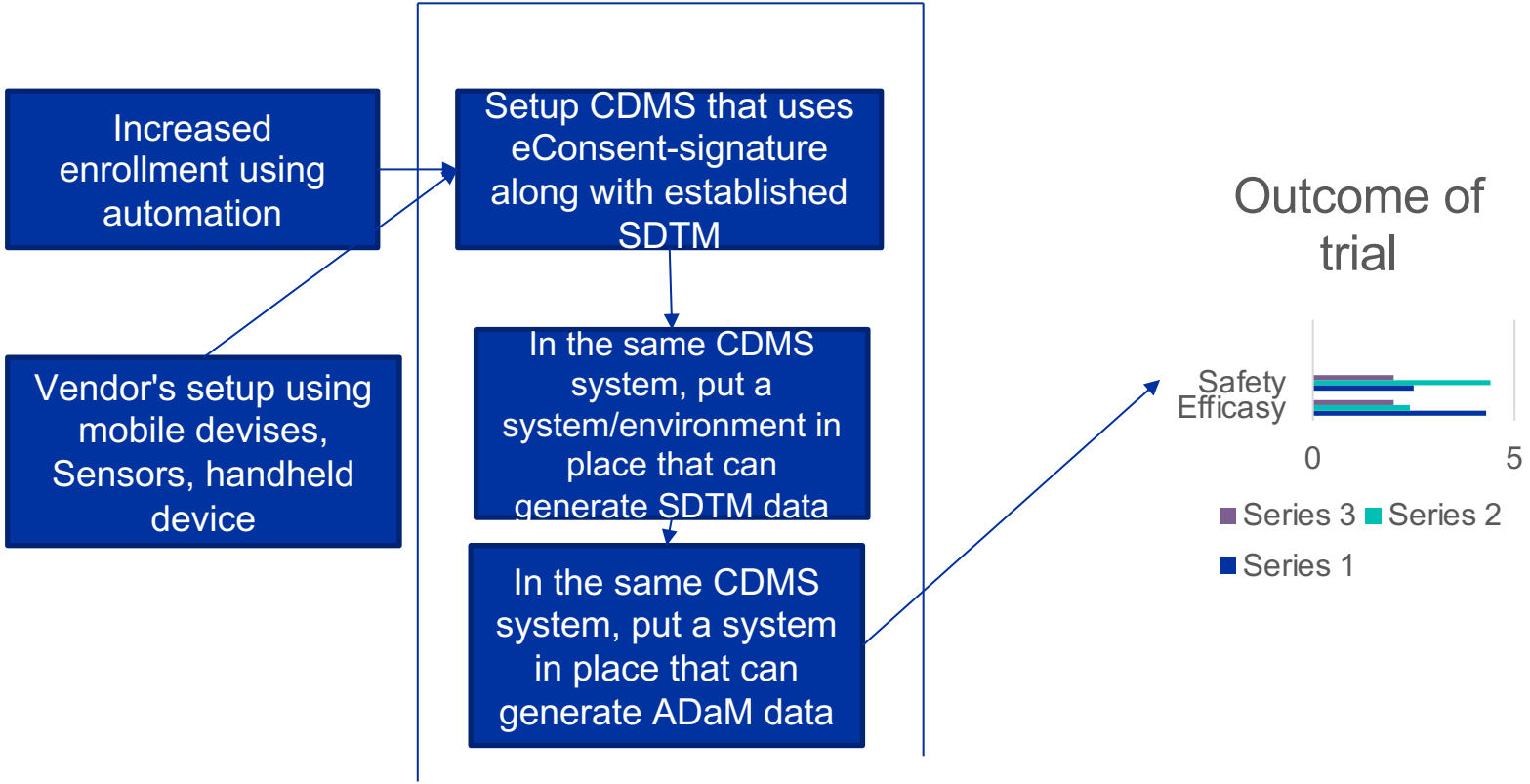
- There can be use of automation tools to fasten the clinical trail conduct as well.
- We can automate the generation of SDTM annotations, couple of CRO’s including pharma companies are doing that.
- We can automate mapping of data from CDASH to SDTM. We can collect data in mobile devices or ePROs or eDairy and make them to be received in SDTM format.
- Why can't we have CDASH/SDTM during database design itself. Why should this start at a later stage as it is happening now.
- Once we finalize the database structure, we know where that data is going to be populated in SDTM, why can't we link in database design.
- At least 80% SDTM/ADAM dataset structure is common in a therapeutic area why can't we link SDTM/ADAM dataset generation to happen within a CDMS CENTRALISED Platform, can't we have a graphical representation of safety and efficacy data in CDMS platform based on the current data that is there in the system?

What is my fantasy?

Traditional flow of data:



What is my fantasy?- Envisioned Ecosystem



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Thanks:

All my Colleagues, Mentors and Managers

Q&A?